

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

12

EUROPEAN PATENT APPLICATION

21 Application number: 88311161.9

51 Int. Cl.4: A 61 N 1/365
A 61 N 1/368

22 Date of filing: 25.11.88

30 Priority: 25.11.87 US 125424

43 Date of publication of application:
31.05.89 Bulletin 89/22

84 Designated Contracting States: DE FR IT NL

71 Applicant: MEDTRONIC, INC.
7000 Central Avenue N.E.
Minneapolis Minnesota 55432 (US)

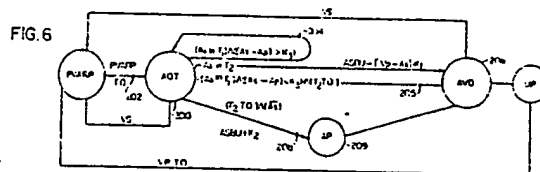
72 Inventor: Funke, Herman D..
Kannheideweg 120
D-5300 Bonn 7 (DE)

Herpers, Lodewyk-Jozef
Graverstraat 153
NL-6466 KV Kerkrade-W (NL)

74 Representative: Tomlinson, Kerry John et al
Frank B. Dehn & Co. European Patent Attorneys Imperial
House 15-19 Kingsway
London WC2B 6UZ (GB)

54 Dual chamber pacemaker with adaptive atrial escape interval.

57 A dual chamber pacemaker having an atrial escape interval which is varied on a beat-to-beat basis in response to the measured time from a ventricular event to the next atrial sensed event. Additionally, a portion of the atrial escape interval is split into a first sensing portion T1 and a second sensing portion T2 wherein atrial sense events occurring during T1 may be ignored by the pacemaker, while atrial sense events falling within T2 are used to compute a new atrial escape interval and are used to resynchronize the pacemaker and are used to inhibit the otherwise scheduled atrial pace event.



ventricular pace event. This form of pacemaker also provides a ventricular sense amplifier for initiating a V-A timer in response to a ventricular sense signal which schedules the generation of an atrial stimulus at the conclusion of the V-A interval unless an atrial sense event occurs to cancel the atrial pace event within the A-V interval.

This prior art DDD form of pacemaker is represented by the state diagram of Fig. 2. Assuming that the machine is in the atrial observation state 24 (AOT), then an atrial sense event (AS) causes state transition 11 which causes the machine to enter the A-V delay state 12 where the A-V delay timer starts to time out an atrial-ventricular escape interval. If the A-V delay timer (AVD) times out (AVTO), then state transition 14 takes place moving the machine to the ventricular pacing state (VP) 16. In this state, the machine delivers a pacing stimulus to the ventricle of the heart. At the conclusion of the pacing pulse, the machine moves via transition 18 to the refractory state 20 during which time the post ventricular-atrial refractory period (PVARP) is timed out. At the conclusion of the post ventricular-atrial refractory period (PVARP), the machine moves via transition 22 to the atrial observation state (AOT). In this state, the pacer is responsive to the atrial sense amplifier as previously described. If atrial activity is not sensed, then the machine will leave the atrial observation state as indicated by state transition 26 whereupon entering the atrial pacing state 28, the machine generates an atrial pacing stimulus. At the conclusion of the pacing pulse reflected by transition 30, the machine re-enters the A-V delay state 12. If a ventricular sense event occurs during this state as indicated by state transition 32, the machine re-enters the refractory state 20.

This state machine description depicts the interaction of the pacer with the heart in response to the various cardiac events which may occur during the various timing cycles of the pacer.

Each of the previously discussed pacing modalities incorporates escape intervals defined as the time period extending from a sense event to the scheduled generation of a succeeding paced event, which are fixed at a discrete value during the operation of the pacer. Modern versions of each of these prior art pacemakers provide for the remote programming of such escape intervals under the direction of a physician. However, once programmed, the intervals are not altered by pacemaker events.

Pacemakers have been proposed and built which alter the escape interval of the pacemaker in response to pacemaker detected cardiac events. An example of one such pacemaker is U.S. Patent No. 4,052,991 to Zacouto as well as U.S. Patent No. Re. 28,341 to Gobeli. The Zacouto machine is a ventricular pacemaker with ventricular sensing which alters the V-V escape interval of the pacemaker depending upon the timing of naturally occurring ventricular events. This pacemaker measures the time interval from a ventricular pace event to a subsequent ventricular sense event and sets the escape interval of the pacemaker to that value. In operation, a Zacouto orthorhythmic pacemaker has a nominal V-V escape interval which results in the metronomic pacing of the ventricle at that rate in the absence of detected atrial ventricular activity. When a ventricular sense event occurs, the orthorhythmic pacemaker may provide an escape interval longer than the nominal escape interval which Zacouto refers to as negative hysteresis. Alternatively the pacer may provide for a shorter escape interval than the nominal value, which Zacouto refers to as positive hysteresis. Consequently, the orthorhythmic pacemaker represents a pacemaker in which the escape interval of the pacemaker is altered on a beat-to-beat basis in response to the detection of ventricular cardiac activity.

The Gobeli pacemaker is a VVI device that exhibits negative hysteresis under the nomenclature of Zacouto since the escape interval of the pacemaker is lengthened in response to a detected ventricular sense event.

More recently, pacers have been proposed which alter the stimulation escape interval based on the evoked QT time interval. See, for example, U.S. Patent No. 4,228,803 to Rickards and 4,305,396 to Wittkamp et al.

BRIEF SUMMARY OF THE INVENTION

The pacemaker of the present invention shares many structures and functions with the previously described pacemakers. However, unlike prior art DDD pacers, this pacer's V-A interval may vary in response to detected atrial activity. Additionally this pacer alters the pacing behavior or stimulation regime of the pacer depending on the temporal relationships between an atrial sense event and the preceding ventricular event. The objective of this pacemaker is to maintain physiologic cardiac contraction patterns over a wide frequency range and to achieve this goal in the presence of a wide variety of conduction faults and arrhythmias.

The functional characteristics of this pacemaker which permit the realization of these goals include the computation of an atrial stimulation back up rate (ASBU) which adapts the intervention frequency of the pacemaker to the observed spontaneous atrial rate; sense factor (SF) which governs the pacer's atrial synchronizing behavior; and intelligent P wave treatment at upper rate (IPTUR) which governs the pacer's action in the presence of competitive rhythms.

The feature denominated SF for sense factor is very desirable in instances where the patient exhibits intermittent atrial function due to disease processes such as sick sinus syndrome or atrial flutter. In the past, such patients would not be candidates for atrial synchronized pacers such as the DDD, but would be best served by a DVI pacer. This is an unfortunate result since many patients may be denied the benefit of atrial synchronized rate responsiveness because of occasional or transient atrial dysfunction. Sense factor addresses this problem by providing the physician with a parameter which can adapt the synchronizing response of the pacer to the disease condition. In operation, the atrial observation time (AOT) of the pacer is split into two intervals denominated T1 and T2. The ratio of these two times is the physician selected sense

factor ($T2/T1 = SF$). Atrial sense events which fall within T1 are not used to resynchronize the pacer yielding a DVI-like behavior, while atrial sense events falling within T2 resynchronize the pacer yielding a DDD-like behavior. Consequently SF permits the pacer to exhibit a smooth transition between DVI and DDD behavior dependent on the temporal relationship between the atrial sense event and its preceding ventricular event.

5 This permits the benefit of atrially based physiologic stimulation to be brought to more patients. Conceptually T1 may be regarded as a post-ventricular atrial refractory period which is adjusted automatically based on the pacer's rate. However, unlike traditional refractory periods, the atrial sense amplifier is "on" and is sensing during this time period. Note that this T1 interval is long at low rates and short at higher rates. The physician can set a large T1 period via SF programming to prohibit or prevent a pacemaker mediated tachycardia without

10 compromising the ability of the pacer to track the faster atrial rates.

The alert reader will recognize that the benefit conferred by SF, which is the ability of the patient's atria to dictate whether the pacer will follow the DDD or DVI regime, could extract a penalty in terms of rate variability. If one recalls that DVI pacing occurs at a fixed lower rate and that DDD pacing occurs at the instantaneous atrial rate, then the ability to move from DDD to DVI and back again could result in large jumps in ventricular stimulation rates. ASBU, the atrial stimulation back-up rate, addresses this problem. This feature is described in detail later. For now it should be considered as a "flywheel" on the pacer's escape interval. The computation of the pacer's atrial escape interval contains "inertial" terms which ensure that the rate accelerates in a physiologically sensible manner.

We now move to the behavior of the pacer at high rates. Once again the matter is described later in detail, however, the IPTUR feature should be examined briefly to understand its relation to the schema. If a sequence of atrial sense events have fallen in T2, then the pacer's ASBU has been shortened to approximate the naturally observed Q-P or V-A time. When the pacer's rate and the heart's rate are similar, one runs the risk of competitive pacing. Competitive pacing occurs when a natural cardiac depolarization and a pacing stimulus occur together close in time. Let us assume that ASBU has scheduled an atrial stimulus 150 ms hence, and at

25 present we sense a naturally occurring atrial event which has occurred in T1. IPTUR dictates that we cancel the scheduled atrial pace event even though it has landed in T1 and would at lower rates be ignored (DVI-like behavior). IPTUR, in essence, sets a window of inhibition which overrides the SF dictated response at higher rates.

An embodiment of the invention will now be described by way of example and with reference to the

30 accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

35 Fig. 1 is a timing diagram showing the relationships between intervals used to describe the invention.

Fig. 2 is a state diagram of a prior art DDD pacer.

Figs. 3, 4 and 5 are hypothetical schematic timing diagrams depicting the pacer timing intervals and the simultaneous electrocardiographic recordings which show the interaction between the pacer and the

40 heart.

Fig. 6 is a state diagram depicting the pacer of the present invention.

Throughout the description, reference will be made to terms defined as follows:

VE is a ventricular event, either sense or pace;

VP is a ventricular pace event generated by the ventricular pulse generator.

45 VS is a ventricular sense event generated by the ventricular sense amplifier.

AP is an atrial pace event generated by the atrial pulse generator.

AS is an atrial sense event generated by the atrial sense amplifier.

$[VE \rightarrow AP]_n$ is the time interval from a ventricular event to the next scheduled AP event for the nth pacing cycle. This corresponds to the V-A escape interval of the pacer.

50 ASBU is the atrial stimulation back-up rate which corresponds to the V-A escape interval of the pacer. It comprises the arithmetic summation of two time intervals and is computed by the pacer in real time. $[PVARP + AOT]$.

PVARP is the post ventricular atrial refractory period. The value is programmable. The total atrial refractory period is equal to the arithmetic sum of PVARP and the A-V delay interval of the pacer.

55 AOT is the atrial observation time. This period extends from the end of the PVARP to the end of the ASBU. $[ASBU - PVARP] = AOT$.

T1 is the first portion of the AOT.

T2 is the second portion of the AOT.

SF is the sense factor of the pacer and is the ratio of $T2/T1$. The value of SF is programmable and should vary from $10.0 > SF > 0.1$.

60

K1 is a programmable constant having a nominal value of 12 ms which is added to the nth value of $[VE \rightarrow AP]$ to generate the n + 1 value of $[VE \rightarrow AP]$ or ASBU when an AS event occurs in T2.

K2 is a programmable constant having a nominal value of 50 ms which is added to the nth value of $[VE \rightarrow AP]$ to generate the n + 1 value of $[VE \rightarrow AP]$ or ASBU when no AS events occur in the AOT.

65 K3 is a programmable constant having a nominal value of 150 ms. This time interval overlaps the last portion of

T2 and ends with the AP event. Any AS event within the K3 portion of T2 is used to compute the next ASBU and is used to inhibit the impending AP event. This provides protection from competitive pacing in the atrium.

As shown in connection with Fig. 1, the "V-A" or atrial escape interval of the pacemaker may be varied on a beat-to-beat basis. The atrial escape or VA interval is defined as the time from a ventricular event (VE) labeled 1 to the next atrial pace event (AP) labeled 2 and may be expressed $[VE \rightarrow AP]_n$. This time interval $[VE \rightarrow AP]_n$ may be shortened for a subsequent pacing cycle $[VE \rightarrow AP]_{n+1}$; if an atrial event occurs within this time interval during a current pacing cycle. Similarly, the subsequent V-A, atrial escape interval $[VE \rightarrow AP]_{n+1}$ of the pacemaker may be extended if no atrial activity is detected within the current interval. The atrial escape interval $[VE \rightarrow AP]_n$ is referred to as the atrial stimulation back-up interval. It may be recomputed on each beat, and it is abbreviated ASBU and labeled 3 in the figure. ASBU will vary between a preset maximum value and a preset minimum value. ASBU reflects the interval from a ventricular event to the next scheduled atrial pace event for any given pacing cycle.

In a DDD mode pacemaker, the atrial refractory period is extended beyond ventricular events. Consequently, the pacer exhibits a post ventricular atrial refractory period (PVARP) labeled 4 in the figure, which renders the pacer refractory or insensitive to atrial depolarizations occurring within this fixed time after the ventricular event, depicted by atrial sense event 8 in the figure. In most DDD pacers, this PVARP is a programmed parameter. In a conventional DDD pacer, the conclusion of the PVARP starts a time window during which the pacer can sense atrial events. For our purposes, we define the time period starting with the end of the atrial refractory period to the time out of the ASBU interval as the atrial observation time, abbreviated AOT and labeled 5 in the figure.

In the present invention, the AOT is split into a first sensing period T1 labeled 6 and a second sensing period T2 labeled 7 where $AOT = T1 + T2$. The ratio of time intervals $T2/T1$ is named SF for sense factor. The sense factor may range from 0.1 to 10.0 and is a physician programmable parameter, $10.0 > SF > 0.1$.

The maximum value of ASBU is defined by physician selection of the lower pacing rate for the pacemaker while the minimum value for ASBU is comparable to the duration of the post ventricular atrial refractory period which is defined by the physician when he selects the atrial refractory period.

In operation, ASBU is shortened when an atrial sense event occurs in T2 depicted by atrial sense event 9 in Fig. 1. In this instance, the pacer shortens the atrial escape interval so that it just exceeds the observed atrial rate by a small amount. In this instance, the value of ASBU is set equal to the time period from the ventricular event to the atrial sense event with the addition of a small increment of time K1, $ASBU_{n+1} = [VE \rightarrow AS]_n + K1$, where the value of K1 is on the order of 12 ms and is programmable.

Consequently, an atrial sense event in the T2 portion of the atrial observation time (AOT) can accelerate the pacer through the ASBU calculation. Additionally this atrial sense event during T2 resynchronizes the pacer by starting the A-V delay timer and also inhibits the otherwise scheduled atrial pace event.

Clearly atrial sense events can also occur during the T1 portion of the atrial observation time as depicted in the figure by atrial sense event 10. From the point of view of controlling ASBU, the occurrence of an atrial sense event during T1 is treated the same as if it fell in the refractory period PVARP. Atrial events sensed during T1 may or may not be used to inhibit the scheduled atrial pace event depending on the temporal proximity between the atrial sense and the scheduled atrial pace events. If the time from the AS event to the AP event is less than a constant K3, then the scheduled AP event is cancelled $[AS \rightarrow AP] < K3$, and the pacer exhibits an atrial inhibited response. If, however, the time from the AS event to the AP exceeds K3, then the pacer will not cancel the AP event and will not exhibit an atrial inhibited behavior. Thus an inhibition window time of width K3 is defined at the end of the V-A escape interval such that any atrial event which occurs during said inhibition window interval prevents the generation of an atrial stimulus at the expiration of said V-A interval.

In the alternative, a cardiac cycle may transpire wherein no atrial sense event occurs. In this case, as in the case where an atrial sense event occurs in PVARP or T1, the value of ASBU is lengthened gradually. In this instance the $n+1$ value of ASBU is set equal to the preceding n value with the addition of a fallback interval K2; $ASBU_{n+1} = ASBU_n + K2$. The value of K2 is in the order of 50 ms and is programmable.

In conclusion, it should be observed that ASBU may be shortened or accelerated by rapidly recurring atrial activity, and ASBU will be lengthened by either the absence of atrial activity or the occurrence of atrial activity early in the cardiac cycle.

Figs. 3, 4 and 5 show schematic representations for a pacemaker according to the present invention. In each figure, a schematic EKG trace is shown in conjunction with the various pacemaker time intervals to depict the interaction of the pacemaker with the heart.

Turning to Fig. 3, cardiac pacing cycle A shows the sequential stimulation of both chambers of the patient's heart at the programmed lower rate limit (LR). The electrogram begins with a spontaneously occurring R-wave at 49 which gives rise to a ventricular sense event at 50, initiating the post ventricular atrial refractory period of the pacemaker shown at 52. At the conclusion of the atrial refractory period, the pacemaker enters the atrial observation time. The first portion of the atrial observation time is labeled T1 in the diagram and begins at 54. At the conclusion of the first portion of the observation time, the second portion of the observation time begins at 56. As shown in Fig. 3, no atrial sense events occur within the atrial observation time. Therefore, at the conclusion of this time period, the pacemaker emits an atrial pacing pulse at 58, depicted as the pacing artifact 59 preceding atrial complex or P-wave 61.

This time interval from a ventricular event 50 to the subsequent generation of an atrial pacing event 58 is

referred to as the atrial escape interval of the pacemaker and is referred to as the atrial stimulation back-up interval or ASBU. Complex A shows a pacemaker which has a programmed post ventricular-atrial refractory period of 200 ms with a V-A escape interval programmed to 600 ms. The sense factor of this pacemaker has been set at 1 thus splitting the atrial observation time which is defined as the time period from the conclusion of the atrial refractory period to the generation of the atrial pacing event 58 into two equal time intervals T1 and T2. Complex A represents the maximum value for ASBU for the programmed settings enumerated above.

After the generation of the atrial pacing event 58, the A-V delay timer of the pacemaker begins timing out the A-V interval shown as 60 in Fig. 3. At the conclusion of this interval, a ventricular pacing event 62 is generated since no ventricular sensed activity was detected by the pacemaker within the A-V interval. The ventricular pace event 62 gives rise to the pacing artifact 63 shown on the schematic EKG prior to the stimulated R-wave 64.

The ventricular event 62 once again starts the post ventricular atrial refractory period timer at 66. At the conclusion of the atrial refractory period, the atrial observation time begins at 68. During the first portion T1 of the atrial observation time, an atrial sense event occurs at 70. This is shown in the schematic EKG as P-wave 72. This P-wave, does not inhibit the scheduled atrial pace event for the cardiac cycle shown in B in Fig. 3, nor does it initiate the A-V timer. In this particular instance, the pacemaker treats atrial event 70 as if it fell within an atrial refractory period, but it does not give rise to a new value of ASBU since ASBU is already at its maximum.

Once again, at the conclusion of the atrial observation time at 72, the pacemaker generates an atrial pace event 74 giving rise to a pacing artifact shown on the schematic EKG at 73 preceding P-wave 75.

The atrial pace event at 74 initiates the A-V delay timer resulting in the generation of a ventricular pacing pulse 76 at the conclusion of the A-V delay time and shown on the schematic EKG as pacing artifact 77 preceding the stimulated R-wave 78. At this point, the pacemaker enters the cardiac cycle C in Fig. 3. The computed atrial stimulation back-up rate for this cardiac cycle is 600 ms based upon the information shown within the preceding cardiac cycles A and B. During this cardiac cycle, however, an atrial sense event 80 occurs during the latter portion of the atrial observation time falling within T2. The atrial sense event 80 truncates the remaining portion of T2 and starts the A-V delay timer at 84. Since no naturally conducted R-wave follows P-wave 86, the A-V delay timer times out at 88 generating the ventricular pacing artifact 87 preceding ventricular complex 89.

In pacing cycle D, the occurrence of the atrial sense event 80 during the atrial observation time of cycle C has accelerated the pacemaker by shortening the atrial escape interval.

ASBU for cardiac cycle D is 510 ms. This value is computed by adding a small hysteresis increment of 10 ms to the observed [VP→AS] time interval of 500 ms of cardiac cycle C. The sense factor (SF) remains constant at 1 thus splitting the 310 ms atrial observation time into equal 155 ms sense windows T1, T2.

During cardiac cycle D no atrial events are detected. Therefore, the pacemaker provides the atrial pacing event 90 at the conclusion of the atrial observation time giving rise to the pacing artifact 91 preceding the provoked P-wave 92 on the EKG. At the conclusion of the A-V delay, the pacemaker generates a ventricular pace event 94 giving rise to the pacing artifact 95 preceding stimulated R-wave 97.

Since there has been no detected atrial activity during cardiac cycle D, the value of ASBU is incremented for cardiac cycle E. A fallback increment K2 is added to the value of ASBU. The fallback increment K2 may vary between 10 and 100 ms and has a nominal value of 50 ms giving rise to the ASBU for cardiac cycle E of 560 ms.

Although the fallback increment may be made a constant, it is also contemplated that this value may be logically coupled to the SF value selected by the physician. In general, large values of SF would correspond to large values of K2, and low SF values would map to small values of K2.

With respect to Fig. 3, the computation of the atrial stimulation back-up interval has been shown. The pacemaker's atrial escape interval was accelerated by atrial event 80 and was extended in the absence of atrial activity as shown in connection with cardiac cycle E.

In operation, the value of ASBU may vary from a maximum imposed by the lower rate programmed by the physician as depicted in cardiac cycles A and B up to a minimum value dictated by the duration of the PVARP.

The operation of the pacemaker at high atrial rates and at various sense factors is shown in connection with Figs. 4 and 5.

Turning to Fig. 4, the lower rate of the pacemaker has remained programmed to the 600 ms value, and the PVARP has remained at 200 ms. In the figure, however, the sense factor has been changed from 1 to .33 yielding a larger T1 portion of the atrial observation time.

In the figure, pacing cycle J begins with spontaneous R-wave 400 which gives rise to ventricular sense event 402 initiating the post ventricular atrial refractory period at 404. At the conclusion of the PVARP, the atrial observation time begins. In this example, the SF is .33.

The absence of atrial activity during the AOT results in the scheduled stimulation of the atria at 410, the conclusion of the atrial observation time as depicted by pacing artifact 412 preceding P-wave 414. This atrial pace event 410 starts the A-V delay time of the pacer at 418. At the conclusion of the A-V delay time, a ventricular pace event 420 is generated as illustrated by pacing artifact 422 preceding R-wave 424.

The events of pacing cycle M are identical to pacing cycle J. Pacing cycles K and L are similar to pacing cycles J and M except that atrial activity occurs during cycles K and L.

In pacing cycle K, the atrial sense event occurs at 426 within the T1 portion 428 of the atrial observation time. The pacer computes the time interval remaining until the next scheduled atrial pace event 430. This time interval [AS→AP] is compared with a physician programmable constant K3. Then the pacer effectively ignores

the atrial sense event in the sense that the machine remains in the atrial observation state. When the computed interval is shorter than K3, the pacer will inhibit the scheduled atrial pace event as more fully described in connection with pacing cycle H.

Note that ASBU for each pacing cycle in Fig. 4 has remained constant. This occurs in the example of Fig. 4 because atrial events in T1 are treated the same as events falling within the refractory period and the increment K2 which may be added to ASBU after each cycle cannot extend the value of ASBU below the lower programmed rate.

Fig. 5 is similar to Fig. 4 in that all programmable values are the same save sense factor which has a value of 3 in Fig. 5. Also, the occurrence of atrial event the same in Figs. 4 and 5.

Turning to Fig. 5, note that due to the change in SF, the atrial sense event 500 has occurred during the first few milliseconds of the T2 portion 502 of the atrial observation time.

In response to AS 500, the pacer enters the A-V delay state wherein the programmed A-V delay is timed out. At the conclusion of this A-V delay 504, a ventricular pace event 506 is generated completing pacing cycle F.

ASBU for pacing cycle G is calculated based on the occurrence of AS 500. The pacer sets ASBU for pacing cycle G equal to the observed time interval from the ventricular event 501 to the atrial sense event 500 of 310 ms with the addition of an increment K1 of 10 ms. Therefore, the value of ASBU for pacing cycle G is 320 ms with an AOT value of 120 ms. Since no atrial sense events occur during pacing cycle G, the ASBU for pacing cycle H is incremented by K2 = 50 ms yielding an ASBU of 370 ms; AOT = 170 ms; T1 = 42.5 ms and T2 = 127.5 ms.

During T1 of cycle H, an atrial sense event occurs 508. The pacer once again computes the time to the next atrial pace event which in this case is approximately 130 ms. $[AS \rightarrow AP] = 127.5$ ms. In the example, we assume a value of K3 of 150 ms and note that $[AS \rightarrow AP] < 150$ ms. This illustrates that while operating near the upper rate limit the duration of T1 and T2 may be quite short which reduces the likelihood that all P-waves will be sensed within T2. In the illustration, the naturally occurring atrial event 508 occurs so close to the scheduled atrial pace event that there is a likelihood that the scheduled AP event would fall within the repolarization or vulnerable time of the atrial and thus compete with the natural atrial rhythm. To avoid this, possibly the pacer inhibits atrial pace events which would occur less than a preset time, i.e. K3 prior to the atrial stimulation time.

The state machine depicted in Fig. 6 describes the differences between the pacer according to the present invention and the pacer disclosed in U.S. Patent No. 4,312,355.

At the conclusion of the post ventricular atrial refractory period, the pacer enters the atrial observation state 200 via state transition 202. The atrial observation time (AOT) is split by the sense factor (SF), and the total duration of the T1 and T2 segments depends on the SF as well as the observed atrial sensing rate. If an atrial sense event occurs during T1 and the computed time period from the atrial sense event AS to the end of the AOT exceeds the value of K3, then the pacer remains in AOT state depicted by loop 204. In this situation, the machine effectively ignores the detected atrial event. If, however, the AS event in T1 gives rise to a value of $[AS \rightarrow AP]$ which is smaller than K3, then the pacer will inhibit the otherwise scheduled atrial pace event AP and move to the A-V delay state 206 (AVD) at the conclusion of the atrial observation time (AOT). This is shown by state transition 205.

Another path for leaving the AOT state 200 is shown by state transition 208. In this instance, there has been no atrial sense event AS, and the atrial observation time has expired at the end of T2. The machine then enters the atrial pace state 209 where the pacer generates an atrial stimulus on the atrial lead.

The machine herein described has been reduced to practice through the use of a commercially available computer coupled to conventional pacer sense amplifiers and output stimulus generators. An annotated software listing written in BASIC and 6502 ASSEMBLER CODE is reproduced as follows:

```

100  rem *** ddd-pacemaker with gliding atrial
      refractory ***
105  rem *** vsap and intelligent p wave treatment
      (ipt) ***
110  rem *** basref15+masref15  h.d.funke aug. 14,
      1983 ***
115  rem *** ipt-time 20494,x * ipt off 20529,0 * ipt on
      20529,251 ***
120  rem *** d00 20020,0 * 20029,0 * 20070,0 * 20079,0 *
      20202,0 ***
125  poke59468,14:poke59459,67
130  print"          Please wait, I'm loading":
      print:print
135  print"          the machine program!"
140  fori=39645to40197:pokei-19645,peek(i):nexti
145  1r$="70":av$="180":hy$="25":sf$=".3":hr$="120":
      wa$=".5":wv$=".5":mo$="1"
150  print"          *** DDD-Autoref-Pacemaker ***":print:
      print:goto160
155  print "      "
160  bl=40:re=150:cali=115:w7=30
165  print"    Lo Rate    ( 50 - 120 PPM)  ?";tab(32);1r$;
170  ifr=0thenprint" ":goto180
175  print"      ";tab(30);:input1r$:print
180  1r=val (1r$):if1r<50or1r>120thenprint"      ":goto165
185  print"    AV Time    ( 20 - 250 ms)  ?";tab(32);av$;
190  ifr=0thenprint" ":goto200
195  print"      ":tab(30);:inputav$:print
200  av=val (av$):ifav<20orav>250thenprint"      ":goto165
205  print"    AV Hyst    ( 00 - 100 ms)  ?";tab(32);hy$;
210  ifr=0thenprint" ":goto220
215  print"      ";tab(30);:inputhy$:print
220  hy=val(hy$):ifhy>av-20orhy>100thenprint"      ":goto205
225  print"    Sense Fact ( 0.1- 1.0    )  ?";tab(32);sf$;

```



```

230  ifr=0thenprint" ":goto240
235  print" ";tab(30);:inputsf$:print
240  sf=val(sf$):ifsf<.1orsf>1thenprint" ":goto225
245  mr=int(60000/(av+re+20))
250  print" Hi Rate (";int(1r+1);:if1r+>99.9thenprint
    " ";
255  ifint(1r+1)<100thenpoke33745,32
260  print"-";int(mr);tab(23);"PPM) ?";tab(32);hr$;
265  ifr=0thenprint" ":goto275
270  print" ";tab(30);:inputhr$:print
275  hr=val(hr$):ifhr<1r+1orhr>mrthenprint" ":goto250
280  print" PWA ( 00 - 2.0 ms) ?";tab(32);wa$;
285  ifr=0thenprint" ":goto295
290  print" ";tab(30);:inputwa$:print
295  wa=val(wa$):ifwa>2thenprint" ":goto280
300  print" PWV ( 00 - 2.0 ms) ?";tab(32);wv$;
305  ifr=0thenprint" ":goto315
310  print" ";tab(30);:inputwv$:print
315  wv=val(wv$):ifwv>2thenprint" ":goto300
320  print" DDD(1), DVI(2), VVI(3) ?";tab(32);mo$;
325  ifr=0thenprint" ":goto335
330  print" ";tab(30);:inputmo$:print
335  mo=val(mo$):ifmo<>1andmo<>2andmo<>3thenprint" ":
    goto320
340  print:print" New entries: press any key."
345  print" New start: run 145":r=1
350  rem *** 1r, av, hy, sf, hr, bl, re, wa, wv, cali,
    w7 ***
355  av=int(av/4):hy=int(hy/4):bl=int(bl/4):re=int(re/4):
    w7=int(w7/4)
360  wa=int(wa*115):wv=int(wv*115)
365  poke20128,bl:poke20251,re:poke20106,wa:poke20229,wv
370  poke20010,ca:poke20060,ca:poke20133,ca
375  poke20183,ca:poke20256,ca:poke20306,ca
380  poke20104,254:ifwa=0thenpoke20104,255:poke20106,1
385  poke20227,253:ifwv=0thenpoke20227,255:poke20229,1

```

```

390  ifmo=1thenpoke20070,251:poke20104,254:ifwa=0thenpoke
      20104,255
395  ifmo=2thenpoke20070,0:poke20104,254:ifwa=0thenpoke
      20104,255
400  ifmo=3thenpoke20070,0:poke20104,255
405  w4=av-b1-w7:w6=av-hy-w7:ws=int(15000/1r)-av-re:rem
      ws=w1+w2
410  w1=int(ws/(sf+1)):w2=ws-w1:tm=int(15000/hr)-re-w6-w7
415  rem *** w1, w2, b1, w4, re, w6, tm, w7 ***
420  ifw1<1thenw1=1
425  ifw2<1thenw2=1
430  ifw4<1thenw4=1
435  ifw6<1thenw6=1
440  iftm<1thentm=1
445  poke20370,tm:poke20390,tm:poke20410,tm:poke20429,w7
450  poke20353,w1:poke20005,tm:poke20055,w2:poke20178,w4:
      poke 20301,w6
455  sys20004:geta$:ifa$<>""thengoto155
460  poke20055,int(peek(20005)*sf):ifpeek(20005)<
      tmthenpoke20005,tm
465  goto455
ready.

```

```

20000  rts
20001  nop
20002  brk
20003  brk
20004  lda      50
20006  stam     20002
20009  lda      115
20011  stam     20003
20014  ldam     59471
20017  ora      251
20019  cmp      251
20021  beq      20045
20023  ldam     59471

```

WAIT P.R.

| | | | |
|-------|------|--|-----------|
| 20026 | ora | 247 | |
| 20028 | cmp | 247 | |
| 20030 | beq | 20048 | |
| 20032 | decm | 20003 | |
| 20035 | bne | 20014 | |
| 20037 | decm | 20002 | |
| 20040 | bne | 20009 | |
| 20042 | jmp | 20528 | |
| 20045 | jmp | 20476 | |
| 20048 | jmp | 20250 - refract. | |
| <hr/> | | | |
| 20051 | nop | | |
| 20052 | orap | 87 | |
| 20054 | lda | 14 | |
| 20056 | stam | 20052 | |
| 20059 | lda | 115 | |
| 20061 | stam | 20053 | |
| 20064 | ldam | 59471 | |
| 20067 | ora | 251 | |
| 20069 | cmp | 251 | WAIT P.R. |
| 20071 | beq | 20095 | |
| 20073 | ldam | 59471 | |
| 20076 | ora | 247 | |
| 20078 | cmp | 247 | |
| 20080 | beq | 20098 | |
| 20082 | decm | 20053 | |
| 20085 | bne | 20064 | |
| 20087 | decm | 20052 | |
| 20090 | bne | 20059 | |
| 20092 | jmp | 20102 | |
| 20095 | jmp | 20365 - atrial stim. rate back-up (ASBU) | |
| 20098 | jmp | 20250 - refract. | |
| <hr/> | | | |
| 20101 | nop | | |
| 20102 | sei | | |
| 20103 | lda | 254 | |
| 20105 | ldx | 57 | |
| 20107 | stam | 59471 | |
| 20110 | dex | | |

| | | | |
|-------|------|-------|---------------|
| 20111 | nop | | |
| 20112 | nop | | STIM A |
| 20113 | nbe | 20110 | |
| 20115 | ldx | 255 | |
| 20117 | stym | 59471 | |
| 20120 | cli | | |
| 20121 | jmp | 20348 | - SLOW DOWN |
| <hr/> | | | |
| 20124 | nop | | |
| 20125 | brk | | |
| 20126 | brk | | |
| 20127 | lda | 10 | |
| 20129 | stam | 20125 | |
| 20132 | lda | 115 | |
| 20134 | stam | 20126 | |
| 20137 | ldam | 59471 | |
| 20140 | ora | 251 | WAIT BLANKING |
| 20142 | cmp | 0 | |
| 20144 | beq | 20168 | |
| 20146 | ldam | 59471 | |
| 20149 | ora | 247 | |
| 20151 | cmp | 0 | |
| 20153 | beq | 20171 | |
| 20155 | decm | 20126 | |
| 20158 | bne | 20137 | |
| 20160 | decm | 20125 | |
| 20163 | bne | 20132 | |
| 20165 | jmp | 20177 | |
| 20168 | jmp | 0 | |
| 20171 | jmp | 0 | |
| <hr/> | | | |
| 20174 | nop | | |
| 20175 | brk | | |
| 20176 | brk | | |
| 20177 | lda | 28 | |
| 20179 | stam | 20175 | |
| 20182 | lda | 115 | |
| 20184 | stam | 20176 | |
| 20187 | ldam | 59471 | |

| | | | |
|-------|------|-------|--------------------------------------|
| 20190 | ora | 251 | |
| 20192 | cmp | 0 | WAIT |
| 20194 | beq | 20218 | <u>REFRACT.</u> |
| 20196 | ldam | 59471 | |
| 20199 | ora | 247 | |
| 20201 | cmp | 247 | |
| 20203 | beq | 20221 | |
| 20205 | decn | 20176 | |
| 20208 | bne | 20187 | |
| 20210 | decn | 20175 | |
| 20213 | bne | 20182 | |
| 20215 | jmp | 20428 | - Wait R for R-inhib??? without VSAP |
| 20218 | jmp | 0 | |
| 20221 | jmp | 20385 | - VSAP |

| | | | |
|-------|------|-------|----------------|
| 20224 | nop | | |
| 20225 | sei | | |
| 20226 | lda | 253 | |
| 20228 | ldx | 57 | |
| 20230 | stam | 59471 | <u>STIM. V</u> |
| 20233 | dex | | |
| 20234 | nop | | |
| 20235 | nop | | |
| 20236 | bne | 20233 | |
| 20238 | ldx | 255 | |
| 20240 | stxm | 59471 | |
| 20243 | cli | | |
| 20244 | jmp | 20250 | - Refract. |

| | | | |
|-------|------|-------|----------------------|
| 20247 | nop | | |
| 20248 | brk | | |
| 20249 | brk | | |
| 20250 | lda | 37 | |
| 20252 | stam | 20248 | |
| 20255 | lda | 115 | |
| 20257 | stam | 20249 | |
| 20260 | ldam | 59471 | <u>WAIT REFRACT.</u> |
| 20263 | ora | 251 | |
| 20265 | cmp | 0 | |

| | | |
|-------|------|--|
| 20267 | beq | 20291 |
| 20269 | ldam | 59471 |
| 20272 | ora | 247 |
| 20274 | cmp | 0 |
| 20276 | beq | 20294 |
| 20278 | decn | 20249 |
| 20281 | bne | 20260 |
| 20283 | decn | 20248 |
| 20286 | bne | 20255 |
| 20288 | jmp | 20538 |
| 20291 | jmp | 0 |
| 20294 | jmp | 0 |
| <hr/> | | |
| 20297 | nop | |
| 20298 | brk | |
| 20299 | brk | |
| 20300 | lda | 32 |
| 20302 | stam | 20298 |
| 20305 | lda | 115 |
| 20307 | stam | 20299 |
| 20310 | ldam | 59471 |
| 20313 | ora | 251 |
| 20315 | cmp | 0 |
| 20317 | beq | 20341 |
| 20319 | ldam | 59471 |
| 20322 | ora | 247 |
| 20324 | cmp | 247 |
| 20326 | beq | 20344 |
| 20328 | decn | 20299 |
| 20331 | bne | 20310 |
| 20333 | decn | 20298 |
| 20336 | bne | 20305 |
| 20338 | jmp | 20428 - Wait R for R-in???? without VSAP |
| 20341 | jmp | 0 |
| 20344 | jmp | 20405 - VSAP |
| <hr/> | | |
| 20347 | nop | |
| 20348 | clc | |
| 20349 | ldam | 20005 |

WAIT R
(after atrial sense)
VSAP - DECIMAL?

| | | | | |
|-------|------|-------|--|--------------------------------|
| 20352 | cmp | 101 | - Lowest rate needed | SLOW DOWN |
| 20354 | bcs | 20361 | | |
| 20356 | adc | 2 | - Slow down by 2x4=8ms | AFTER |
| 20358 | stam | 20005 | | |
| 20361 | jmp | 20127 | - Blanking | <u>ATRIAL STIM</u> |
| 20364 | nop | | | |
| 20365 | sec | | | |
| 20366 | ldam | 20005 | | |
| 20369 | cmp | 49 | | |
| 20371 | bcc | 20381 | | |
| 20373 | sbcm | 20052 | - This time from wait P.R. elapse | |
| 20376 | adc | 5 | - Soothing rate changes | ASBU |
| 20378 | stam | 20005 | - Store new time back | |
| 20381 | jmp | 20300 | - Wait R | |
| 20384 | tax | | | |
| 20385 | sec | | | |
| 20386 | ldam | 20005 | | |
| 20389 | cmp | 49 | - Control for already existing maximal rate | |
| 20391 | bcc | 20401 | | VSAP |
| 20393 | sbcm | 20175 | - This time from wait R could not elapse because of early R. | AFTER ATRIAL <u>STIM</u> |
| 20396 | sbc | 4 | | |
| 20398 | stam | 20005 | - Time for acceleration stored back | |
| 20401 | jmp | 20250 | - Refract. | |
| 20404 | tax | | | |
| 20405 | sec | | | |
| 20406 | ldam | 20005 | | |
| 20409 | cmp | 49 | - Max rate checking required? | |
| 20411 | bcc | 20421 | | VSAP |
| 20413 | sbcm | 20298 | - This time could not elapse because of early R. | AFTER ATRIAL |
| 20416 | sbc | 4 | | <u>SENSE</u> |
| 20418 | stam | 20005 | - Later time stored back | |
| 20421 | jmp | 20250 | - Refract. | |

| | | | |
|-------|------|-------|------------------------|
| 20424 | tax | | |
| 20425 | nop | | |
| 20426 | brk | | |
| 20427 | brk | | |
| 20428 | lda | 7 | |
| 20430 | stam | 20426 | |
| 20433 | lda | 125 | |
| 20435 | stam | 20427 | WAIT R |
| 20438 | ldam | 59471 | (for R-inhibition) |
| 20441 | ora | 251 | (if R, <u>no</u> VSAP) |
| 20443 | cmp | 0 | |
| 20445 | beq | 20469 | |
| 20447 | ldam | 59471 | |
| 20450 | ora | 247 | |
| 20452 | cmp | 247 | |
| 20454 | beq | 20472 | |
| 20456 | decm | 20427 | |
| 20459 | bne | 20438 | |
| 20461 | decm | 20426 | |
| 20464 | bne | 20433 | |
| 20466 | jmp | 20225 | - Stim R. |
| 20469 | jmp | 0 | |
| 20472 | jmp | 20250 | - Refractory |
| <hr/> | | | |
| 20475 | tax | | |
| 20476 | tax | | |
| 20477 | tax | | |
| 20478 | tax | | |
| 20479 | tax | | |
| 20480 | lda | | |
| 20482 | stam | 20020 | |
| 20485 | nop | | |
| 20486 | ldam | 20002 | |
| 20489 | adcm | 20055 | |
| 20492 | nop | | |
| 20493 | cmp | 60 | - 1PT-Time |
| 20495 | bcs | 20513 | |
| 20497 | nop | | |

| | | | |
|-------|------|-------|----|
| 20498 | lda | 79 | |
| 20500 | stam | 20094 | |
| 20503 | lda | 124 | 5 |
| 20505 | stam | 20093 | |
| 20508 | jmp | 20023 | |
| 20511 | nop | | 10 |
| 20512 | nop | | |
| 20513 | lda | 78 | |
| 20515 | stam | 20094 | 15 |
| 20518 | lda | 134 | |
| 20520 | stam | 20093 | |
| 20523 | jmp | 20023 | 20 |
| 20526 | tax | | |
| 20527 | tax | | |
| 20528 | lda | 251 | 25 |
| 20530 | stam | 20020 | |
| 20533 | jmp | 20054 | |
| 20536 | tax | | 30 |
| 20537 | tax | | |
| 20538 | lda | 78 | |
| 20540 | stam | 20094 | 35 |
| 20543 | lda | 134 | |
| 20545 | stam | 20093 | |
| 20548 | jmp | 20000 | 40 |
| 20551 | tax | | |
| 20552 | tax | | 45 |
| | | | 50 |

Claims

1. A pacemaker having:

- (a) an atrial sense amplifier for producing an atrial sense event signal (AS) in response to an atrial depolarization;
- (b) a ventricular sense amplifier for producing a ventricular sense event signal (VS) in response to a ventricular depolarization;
- (c) an atrial pulse generator for producing an atrial stimulating pulse in response to an atrial pace event signal (AP);
- (d) a ventricular pulse generator for producing a ventricular stimulating pulse in response to a ventricular pace event signal (VP);
- (e) a V-A timer means for timing a V-A escape interval and for generating an atrial pace event signal

at the conclusion of said V-A escape interval, and wherein said V-A escape interval is initiated by the occurrence of a ventricular event;

(f) an A-V timer means for timing an A-V escape interval and for generating a ventricular pace event signal at the conclusion of said A-V escape interval and wherein said A-V escape interval may be initiated by the occurrence of an atrial event;

(g) means for dividing said V-A escape interval into a first time interval T1 and a second time interval T2 such that atrial sense events occurring within said first time interval T1 increase the duration of a subsequent V-A escape interval and such that atrial sense events occurring within said second time interval T2 decrease the duration of a subsequent V-A escape interval.

2. A pacemaker as claimed in claim 1 wherein atrial sense events which occur within said first time interval do not initiate said A-V escape interval and atrial sense events which occur during said second T2 time interval do initiate said A-V escape interval.

3. A pacemaker as claimed in claim 1 or 2 further including inhibition window timer means defining an inhibition window interval at the end of said V-A escape interval such that any atrial event which occurs during said inhibition window interval prevents the generation of an atrial stimulus at the expiration of said V-A interval.

4. A pacemaker having:

(a) an atrial sense amplifier for producing an atrial sense event signal (AS) in response to an atrial depolarization;

(b) a ventricular sense amplifier for producing a ventricular sense event signal (VS) in response to a ventricular depolarization;

(c) an atrial pulse generator for producing an atrial stimulating pulse in response to an atrial pace event signal (AP);

(d) a ventricular pulse generator for producing a ventricular stimulating pulse in response to a ventricular pace event signal (VP);

(e) a V-A timer means for timing a V-A escape interval and for generating an atrial pace event signal at the conclusion of said V-A escape interval, and wherein said V-A escape interval is initiated by the occurrence of a ventricular event;

(f) an A-V timer means for timing an A-V escape interval and for generating a ventricular pace event signal at the conclusion of said A-V escape interval and wherein said A-V escape interval may be initiated by the occurrence of an atrial event;

(g) means for dividing said V-A escape interval into a first time interval T1 and a second time interval T2 such that atrial sense events which occur during said first time interval do not initiate said A-V escape interval, and such that atrial sense events which occur during said second time interval do initiate said A-V escape interval.

5. A pacemaker as claimed in claim 4 further comprising inhibition window timer means defining an inhibition window interval at the end of said V-A escape interval such that any atrial event which occurs during said inhibition window interval prevents the generation of an atrial stimulus at the expiration of said V-A interval.

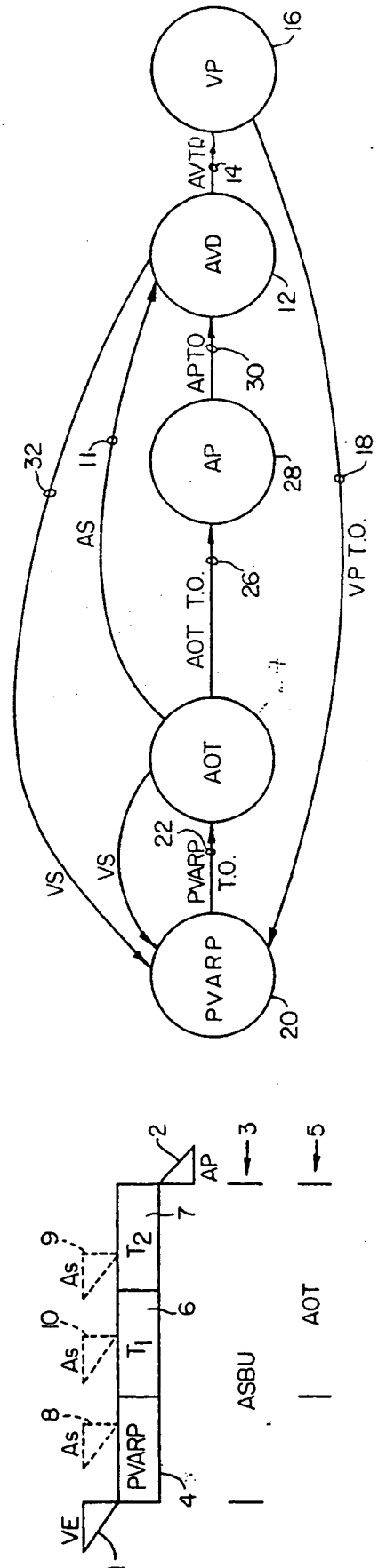
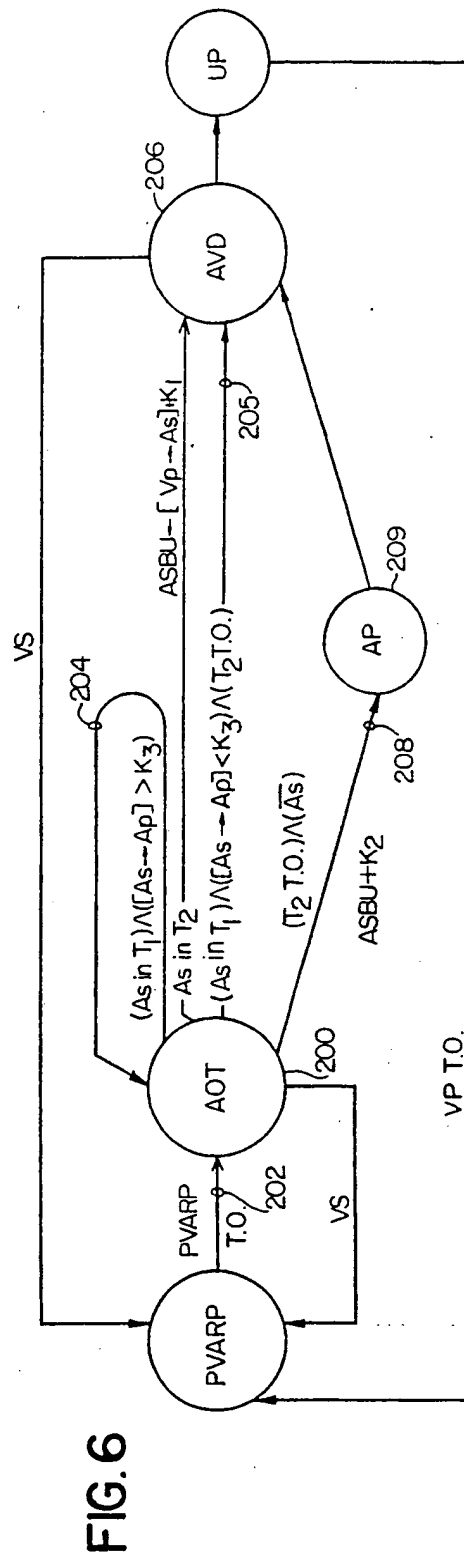
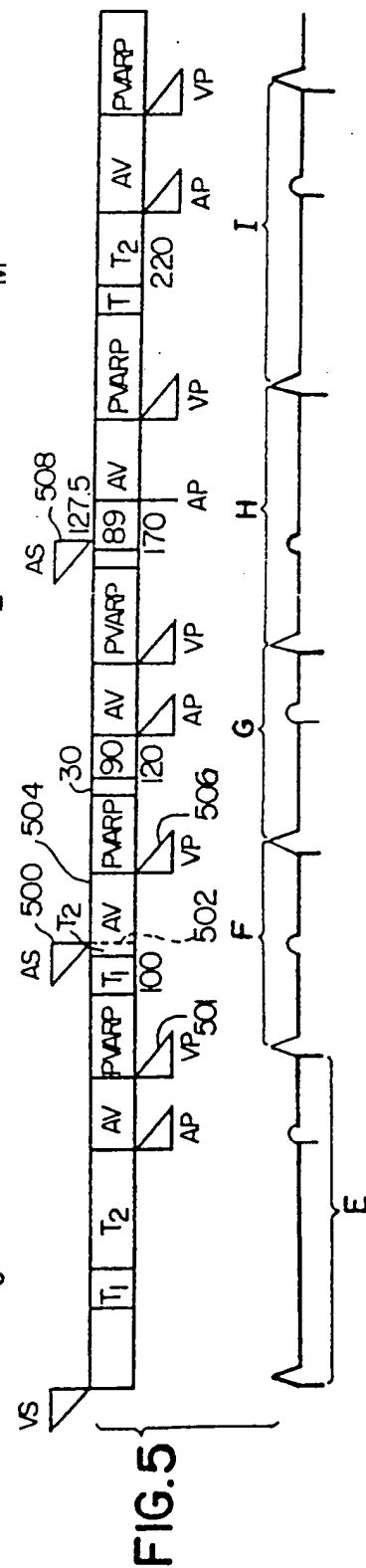
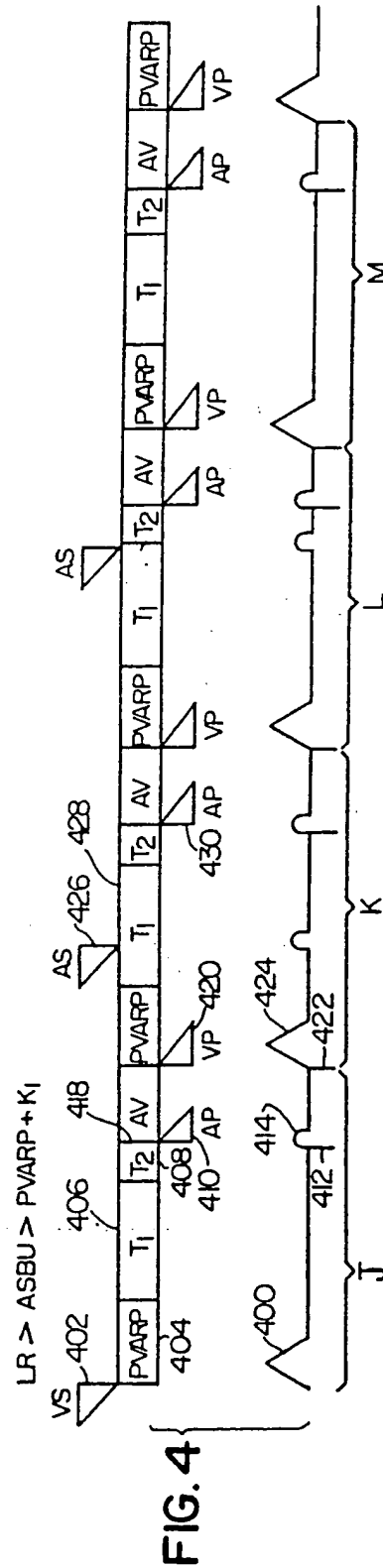
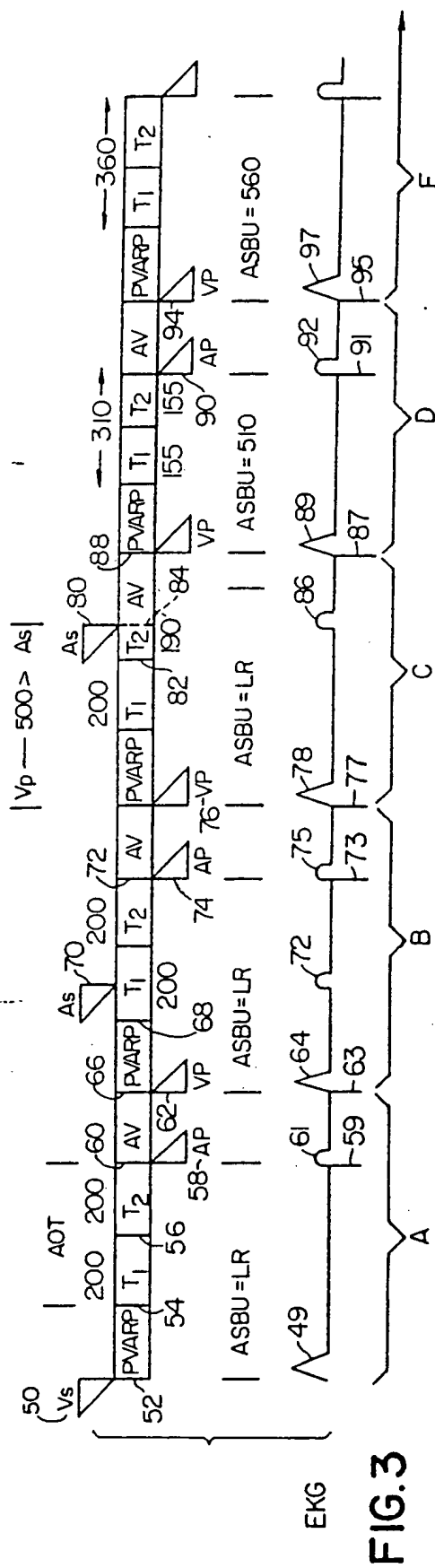


FIG. 2
PRIOR ART



⑫

EUROPEAN PATENT APPLICATION

②① Application number: 88311161.9

⑤① Int. Cl.⁴: **A 61 N 1/365**
A 61 N 1/368

②② Date of filing: 25.11.88

③③ Priority: 25.11.87 US 125424

④③ Date of publication of application:
31.05.89 Bulletin 89/22

⑧④ Designated Contracting States: DE FR IT NL

⑧⑧ Date of deferred publication of search report:
13.09.89 Bulletin 89/37

⑦① Applicant: **MEDTRONIC, INC.**
7000 Central Avenue N.E.
Minneapolis Minnesota 55432 (US)

⑦② Inventor: **Funke, Herman D.**
Kannheideweg 120
D-5300 Bonn 7 (DE)

Herpers, Lodewyk-Jozef
Graverstraat 153
NL-6466 KV Kerkrade-W (NL)

⑦④ Representative: **Tomlinson, Kerry John et al**
Frank B. Dehn & Co. European Patent Attorneys Imperial
House 15-19 Kingsway
London WC2B 6UZ (GB)

⑤④ **Dual chamber pacemaker with adaptive atrial escape interval.**

⑤⑦ A dual chamber pacemaker having an atrial escape interval which is varied on a beat-to-beat basis in response to the measured time from a ventricular event (1) to the next atrial sensed event (8,9,10). Additionally, a portion (5) of the atrial escape interval is split into a first sensing portion T1 (6) and a second sensing portion T2 (7) wherein atrial sense events (8,9,10) occurring during T1 (6) may be ignored by the pacemaker, while atrial sense events (8,9,10) falling within T2 (7) are used to compute a new atrial escape interval and are used to resynchronize the pacemaker and are used to inhibit the otherwise scheduled atrial pace event (2).

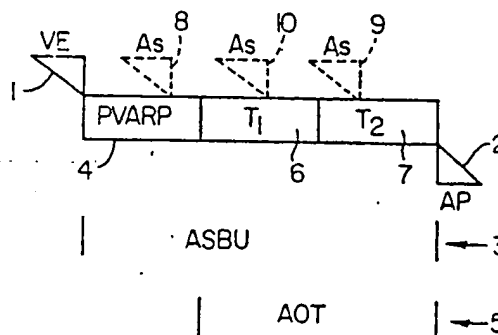


FIG. 1



EP 88 31 1161

| DOCUMENTS CONSIDERED TO BE RELEVANT | | | |
|---|---|---|---|
| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (Int. Cl.4) |
| A | EP-A-0 201 990 (INTERMEDICS) * Page 7, line 4 - page 14, line 19; figure 2 * ---- | 1-5 | A 61 N 1/365 A 61 N 1/368 |
| A | EP-A-0 241 102 (INTERMEDICS) * Column 11, line 22 - column 12, line 6; figure 7 * ---- | 1,2,4 | |
| A | EP-A-0 218 789 (SIEMENS) * Whole document * ---- | 1,2,4 | |
| A | THE AMERICAN JOURNAL OF CARDIOLOGY, vol. 52, no. 1, July 1983, pages 88-91; J.W. RUBIN et al.: "Current physiologic pacemakers: a serious problem with a new device" ----- | | |
| | | | TECHNICAL FIELDS SEARCHED (Int. Cl.4) |
| | | | A 61 N |
| The present search report has been drawn up for all claims | | | |
| Place of search THE HAGUE | | Date of completion of the search 03-04-1989 | Examiner SCHMIERER U.J. |
| CATEGORY OF CITED DOCUMENTS | | | |
| X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document | | T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document | |